Office Action Summary	Application No.	Applicant(s)	
	10/777,838	WEDEL ET AL.	
	Examiner	Art Unit	
	DANA SHIN	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7-17,25-42,44 and 45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7-17,25-42,44 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20110203*
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 24, 2010 has been entered.

Status of Claims

Claims 1-3, 7-17, 25-42, and 44-45 are currently pending and under examination on the merits in the instant case.

Response to Arguments

Applicant's arguments with respect to claims 1-3, 7-17, 25-42, and 44 rejected under 35 U.S.C. 103(a) filed with the RCE have been considered but are moot in view of the new ground of rejection. See below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 7-17, 25-42, and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennett et al. (US 6,096,722 citation of record) in view of Yacysyhn et al. (Current Opinion in Molecular Therapeutics, 1999, 1:332-335), Sandborn et al. (US 5,846,983), Kono et al. (US 6,730,702 B1), Karp et al. (Digestive Disease and Sciences, 1988, 33:85S-87S), Sachetto et al. (US 7,341,741 B1, citation of record), Yacyshyn et al. (Alimentary Pharmacology & Therapeutics, 2002, 16:1761-1770, citation of record), Patel et al. (European Journal of Gastroenterology & Hepatology, 1995, 7:1037-1041, citation of record), Svaninger et al. (Scandinavian Journal of Gastroenterology, 1993, 28:695-700, applicant's citation), and Sandborn (Trends in Inflammatory Bowel Disease, 1996, 51-63, applicant's citation).

Bennett et al. teach a method of treating an animal having inflammatory bowel disease (IBD) comprising administering to said animal a prophylactic or therapeutic amount of ISIS 2302 targeted to ICAM-1, whereby IBD is prevented or treated, wherein ISIS 2302 is formulated in a penetration enhancer. See claims 9-11, 16-18. They also teach a pharmaceutical formulation (so-called "Formulation 2b", "Formulation 2e", or "Formulation 2f") of ISIS 2302 with

hydroxypropyl methyl cellulose (HPMC). See column 65. They show that the Formulation 2b", "Formulation 2e", and "Formulation 2f" are formulated as "rectal enemas" and administered to a subject (a dog) into the intended target site (e.g., colon) of the subject, wherein the local tissue (e.g., colon tissue) retains ISIS 2302 effectively when it is delivered by rectal enema in HPMC compared to ISIS 2302 without HPMC. See Examples 47-48. See the "24h" CGE data in Table 11. They teach that the "absolute bioavailability" for rectal enemas of ISIS 2302 is 24.5%, whereas that for intrajejunally administered ISIS 2302 is 20.3% when the "two different modes of administration" were tested in rats. See Example 48. In human subjects with UC, they teach that ISIS 2302 enema "demonstrated good tolerability and tissue uptake." See Example 55. They also teach that it is within the technical grasp of one of ordinary skill in the art to determine the optimal dose of ISIS 2302 by evaluating various safety/toxicology data and pharmacokinetics parameters. See columns 62, 69-71. Bennett et al. do not explicitly teach that the IBD claimed to be treated in U.S. Patent No. 6,096,722 is pouchitis.

Yacyshyn et al. (1999) corroborate the teachings of Bennett et al. as they teach that ISIS 2302 is safe and clinically effective to treat inflammatory bowel disease, Crohn's disease and ulcerative colitis, and that as of 1999, they have "developed preliminary preclinical evidence of pharmacology and tolerability of alternative routes of delivery/formulation of ISIS-2302", including "the enema route for ulcerative colitis" (emphasis added). See page 335.

Sandborn et al. teach a method of treating an inflammatory bowel disease (IBD) by "locally administering" a therapeutic agent (see claim 1), wherein the IBD is UC (see claim 2), wherein the IBD is CD (see claim 3), wherein the IBD is pouchitis (see claim 4), wherein the therapeutic agent is administered "by rectal enema" (see claim 5). They further teach that the therapeutic agent can be directly delivered to the inflamed sites of an IBD patient "by

administration of an enterically coated unit dosage form.", so as to "substantially delay the release of" the therapeutic agent "until it reaches its target site of action", wherein the enteric coating polymer is hydroxypropylmethylcellulose (HPMC). See columns 2 and 4. They teach that the enema formulation (e.g., preloaded syringe) allows direct, local delivery of the therapeutic agent and "inhibits its escape from the target site." See column 3.

Kono et al. teach a method of treating IBD, wherein the IBD is "a disease selected from the group consisting of an intestinal lesion accompanied by Crohn's disease or Behcet's disease, ulcerative colitis, hemorrhagic rectal ulcer and ileum pouchitis." (see claim 3). They report that an anti-inflammatory drug was suspended in water and "injected through the anus twice a day for about 4 months" to the patient with ilueum pouchitis, with a resultant effect that the ileum pouchitis was "cured without any cicatricial stenosis." See column 10. They also report that the rectal administration of the same drug (thereby directly administering into the intestine) had clinical effects (e.g., reduced inflammation) for UC as well as CD. See columns 7-8.

Karp et al. teach that an anti-inflammatory agent in an enema formulation is useful for treating inflammatory bowel disease including CD co-occurring with pouchitis, wherein the anti-inflammatory agent is able to "directly inhibit immune functions associated with tissue destruction". See page S86, left column. They teach that severe side effects occur when an anti-inflammatory agent is systemically delivered for IBD treatment as a result of the "systemic absorption" of the agent "before it is delivered to the site of the inflammation." See page S86, left column. They report that all six patients with severe UC "showed a rapid decrease in inflammation" in 7-10 days when tixocortol pivalate retention enemas were used nightly, and that a patient with CD with "very active pouchitis" showed "cessation of inflammation within

five days" when the retention enemas were applied "directly to the pouch". See page 86S, right column.

Sachetto et al. teach a method of treating IBD comprising "contacting the diseased mucosa of the gastrointestinal tract" with a therapeutic agent (see claim 1), wherein the IBD is "pouchitis" (see claim 2), wherein the IBD is "left sided ulcerative colitis" (see claim 3), wherein the IBD is "Crohn's disease" (see claim 4), wherein the therapeutic agent is "rectally administered in the form of an rectally administrable pharmaceutical composition" (see claim 8), wherein the therapeutic agent is "in the form of a composition comprised of a liquid enema containing HPMC" (see claim 11) or "in the form of a composition comprised of a foam enema containing HPMC" (see claim 12). Sachetto et al. teach that pouchitis treatment regimen involves reducing PDAI scores to 3 points or 2 points or 1 or zero point, wherein "improvement" of pouchitis is "defined as a reduction in the PDAI score of 3 points or more". See columns 9-10.

Consistent with Bennett et al. (see columns 62, 69-71), Yacyshyn et al. (2002) teach that it is within the technical grasp of one of ordinary skill in the art to determine the optimal dose of ISIS 2302 by evaluating various safety/toxicology data and pharmacokinetics parameters. For example, they show that they were able to determine that 300-350 mg intravenous infusion of ISIS 2302 is therapeutically effective for treating CD by evaluating various pharmacokinetics parameters, wherein the treatment effects are also determined based on the CDAI scores, wherein lowered/reduced scores indicate treatment effects.

Patel et al. teach that pouchitis, CD, and UC are IBD characterized by clinical symptoms such as diarrhea, rectal bleeding, abdominal pain, fever, and endoscopic evidence of mucosal inflammation. They teach that patients with pouchitis, CD, and UC show a significantly high level of plasma ICAM-1. They teach that pouchitis can co-occur in UC patients and that the

clinical symptoms for both pouchitis and UC are similar, and thus, suggest a similar immunological mechanisms underlying both pouchitis and UC such that "pouchitis might represent a reactivation of the immunological mechanisms that brought about ulcerative colitis." (emphasis added). See page 1040.

Svaninger et al. teach that pouchitis develop in patients who were operated on for UC. They teach that their long-term study revealed that "the pouch inflammation proved eventually to be Crohn's disease in four patients (2.2%)." (emphasis added). See the abstract. They teach that the conventional antibiotic drug metronidazole also contains "an anti-inflammatory component and pouchitis has been shown to respond favorably to local application of steroids." (emphasis added). See page 699. Further, consistent with the suggestions of Patil et al. such that the underlying immunological mechanisms for both pouchitis and UC are commonly shared, Svaninger et al. teach that "pouchitis, occurring predominantly in patients with ulcerative protocolitis, with the highest incidence in patients with extracolonic manifestations, may be caused by a genetically determined alteration of the immunologic reaction to intestinal stasis and antigenic factor." (emphasis added). See page 699.

Sandborn (1996) teaches that pouchitis is a "unique form of recurrent inflammatory bowel disease (IBD) specific to the ileal reservoir." and that pouchitis is an "increasingly common form of IBD." and that "pouchitis is a novel form of IBD specific to the ileal pouch of patients with a history of UC." (emphasis added). See pages 52 and 54.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the claimed IBD treatment methods of Bennett et al. to reduce pouchitis symptoms by reducing PDAI scores.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation, because at the time the invention was made, it was widely recognized in the art that pouchitis is a form of inflammatory bowel disease (IBD) as explicitly taught by cited prior art references (especially see Sandborn (1996)), some of which showed that relevant artisans invented IBD treatment methods that are useful to treat all three forms of IBD (pouchitis, UC, and CD) by rectally administering an enema formulation of a therapeutic agent as taught by Sandborn et al. (US 5,846,983), Kono et al. (US 6,730,702 B1), and Sachetto et al. (US 7,341,741 B1), and because there were also suggestions that the underlying immunological and/or inflammatory mechanisms for causing pouchitis are commonly shared with those for causing UC, and thus pouchitis and UC were suggested to be closely interrelated as taught by Patil et al. and Svaninger et al., and because pouchitis patients as well as UC and CD patients were shown to have elevated plasma ICAM-1 compared to normal subjects as taught by Patil et al. Hence, there were a sufficient amount of suggestions that one can interchangeably use UC/CD treatment method to treat pouchitis, or alternatively, it was suggested that one can perform the same treatment method steps for pouchitis patients as well as UC and CD patients as explicitly claimed in the IBD method inventions of Sandborn et al. (US 5,846,983), Kono et al. (US 6,730,702 B1), and Sachetto et al. (US 7,341,741 B1). As such, one of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success in treating pouchitis by performing the treatment method steps claimed and disclosed in the Bennett et al. reference.

In addition, a person of ordinary skill in the art would have reasonably expected a successful pouchitis treatment (e.g., a reasonable expectation of remission in patients) with an enema formulation of 240 mg of ISIS 2302 at the time the invention was made, because enema

formulation of ISIS 2302 was known to have clinical effects for UC when delivered rectally to human subjects as taught by Yacyshyn et al. (1999) and Bennett et al. (see Example 55) and when delivered rectally to animal subjects (dogs, rats) as taught by Bennett et al. (see Examples 47-48), who also showed that the "absolute bioavailability" for rectal enemas of ISIS 2302 is greater when compared to that for intrajejunally administered ISIS 2302, and because determining optimal doses and dosing schedules for ISIS 2302 that are sufficient to reduce disease index scores (e.g., CDAI, PDAI) and increase remission rates was within the ordinary skill and technical grasp at the time the invention was made as suggested by Yacyshyn et al. (2002), and because directly reducing mucosal inflammation at the site of inflammation by local enema administration of an anti-inflammatory agent was shown to cease inflammation in the pouch in the pouchitis subject and thus the direct/local delivery route was suggested to be more effective than the systemic delivery route as taught by Karp et al., and because rectal administration of enema formulation for treating pouchitis was an art-recognized methodology as evidenced by the inventive methods claimed in Sandborn et al. (US 5,846,983), Kono et al. (US 6,730,702 B1), and Sachetto et al. (US 7,341,741 B1). In addition, it was also an art-recognized fact, at the time the invention was made, that ISIS 2302 is capable of producing a "durable remission" or "highly durable remissions" in IBD patients (e.g., "in almost half of the treated patients") as reported in the art as early as the year of 1999 by Yacyshyn et al. (1999), see page 334-335, as further validated in the subsequent report in 2002. See page 1767 of Yacyshyn et al. (2002): "In this trial of an antisense oligonucleotide to ICAM-1, clinical remission rates occurred in over 41% of all treated subjects, and in 53% of those patients who received more than three of the 12 intended ISIS 2302 infusions. A trend towards more rapid remission was noted in the 350-mg cohort,...The disease response with the 300-mg dose of ISIS 2302 was, if

anything, more durable. Most subjects had clinical disease improvement evident in the 4 weeks following their treatment moth, with additional improvement and remissions seen through to week 12. The mean duration of remission was >4 months, with two subjects in remission for more than 200 days." (emphasis added). Moreover, Bennett et al. also reported that "five of these seven ISIS 2302-treated patients remained in remission, and none of the placebo-treated patients were in remission." at day 180, the end of the treatment for CD patients (emphasis added). See column 70. Hence, the ability of ISIS 2302 for producing remissions in treated patients having IBD was reasonably expected at the time the invention was made, and it was within the technical grasp of one of ordinary skill in the art to rectally administer a therapeutic agent to treat chronic pouchitis patients, wherein 64% of patients with chronic pouchitis improved based on the reduced PDAI scores by 3 points or more after four weeks of treatment when the clinical score, endoscopy score, and histology score were evaluated as taught by Sachetto et al., wherein Kano et al. also showed that an anti-inflammatory drug "injected through the anus twice a day for about 4 months" to the patient with ilueum pouchitis produced an effect that "cured without any cicatricial stenosis." (see column 10), wherein Karp et al. also showed a patient with CD with "very active pouchitis" had "cessation of inflammation within five days" when the retention enemas were applied "directly to the pouch". (see page 86S). Taken together, the methods of claim 44 and claim 45, which reflect some aspects of the results disclosed in Example 17 of the instant specification, would have been reasonably expected at the time the invention was made in light of the ample evidence suggesting the ability of ISIS 2302 for producing durable remissions in IBD patients and the clinical treatment effects (reduced/ceased inflammation) in chronic/active pouchitis patients treated with rectal/local administration of a therapeutic agent.

In view of the foregoing, the claims taken as a whole would have been prima facie obvious at the time the invention was made.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 recites the limitation "said reduction" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 45 recites the limitation "said patient" in line 1. There is insufficient antecedent basis for this limitation in the claim. Note that line 3 also recites "said patient".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference

claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 7-17, 25-42, and 44-45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-11, 16, and 18 of U.S. Patent No. 6,096,722 in view of Sandborn et al. (US 5,846,983) and Patel et al. (European Journal of Gastroenterology & Hepatology, 1995, 7:1037-1041, citation of record) and Yacyshyn et al. (Alimentary Pharmacology & Therapeutics, 2002, 16:1761-1770, citation of record).

Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to use the methods claimed in U.S. Patent No. 6,096,722 to treat pouchitis by rectal administration, thereby arriving at the instant claims, because IBD treatment methods claimed in U.S. Patent No. 6,096,722 were suggested to be

applicable to treat pouchitis as evidenced by the teachings (see claims 1 and 4) of Sandborn et al., and because the targeted gene ICAM-1 claimed in U.S. Patent No. 6,096,722 was known to be elevated in pouchitis patients as well as in UC and CD patients as taught by Patel et al. In addition, arriving at the claimed doses, dosing schedules that result in durable remissions would have been obvious in view of the teachings of Yacyshyn et al. Hence, the invention defined in the instant application is an obvious variation of the invention defined in U.S. Patent No. 6,096,722.

Claims 1-3, 7-17, 25-42, and 44-45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 6, and 9 of U.S. Patent No. 6,169,079 B1 in view of Sandborn et al. (US 5,846,983) and Patel et al. (European Journal of Gastroenterology & Hepatology, 1995, 7:1037-1041, citation of record) and Yacyshyn et al. (Alimentary Pharmacology & Therapeutics, 2002, 16:1761-1770, citation of record).

Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to use the methods claimed in U.S. Patent No. 6,169,079 B1 (methods "of treating a human having a disease with an inflammatory component which is modulated by changes in human intercellular adhesion molecule-1") to treat pouchitis by rectal administration, thereby arriving at the instant claims, because treatment methods claimed in U.S. Patent No. 6,169,079 B1 were suggested to be applicable to treat IBD (See Example 20), and because pouchitis was known to be IBD as evidenced by the teachings (see claims 1 and 4) of Sandborn et al., and because the targeted gene ICAM-1 claimed in U.S. Patent No. 6,169,079 B1 was known to be elevated in pouchitis patients as well as in UC and CD patients as taught by Patel et al., who also taught that the elevated ICAM-1 contributes to the

inflammatory component/immune reactivation of pouchitis. In addition, arriving at the claimed doses, dosing schedules that result in durable remissions would have been obvious in view of the teachings of Yacyshyn et al. Hence, the invention defined in the instant application is an obvious variation of the invention defined in U.S. Patent No. 6,169,079 B1.

Claims 1-3, 7-17, 25-42, and 44-45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,747,014 B2 in view of Sandborn et al. (US 5,846,983) and Patel et al. (European Journal of Gastroenterology & Hepatology, 1995, 7:1037-1041, citation of record) and Yacyshyn et al. (Alimentary Pharmacology & Therapeutics, 2002, 16:1761-1770, citation of record).

Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to use the enema formulation for rectally administering ISIS 2302 claimed in U.S. Patent No. 6,747,014 B2 to treat pouchitis, thereby arriving at the instant claims, because the enema formulation of U.S. Patent No. 6,747,014 B2 taught to be useful for treating IBD by targeting "various areas of the gut" (see columns 2, 55), and because pouchitis was known to be IBD (see claims 1 and 4 of Sandborn et al.), and because the targeted gene ICAM-1 that is targeted by SEQ ID NO:1 in U.S. Patent No. 6,747,014 B2 was known to be elevated in pouchitis patients as well as in UC and CD patients (thus IBD patients) as taught by Patel et al. In addition, arriving at the claimed doses, dosing schedules that result in durable remissions would have been obvious in view of the teachings of Yacyshyn et al. Hence, the invention defined in the instant application is an obvious variation of the invention defined in U.S. Patent No. 6,747,014 B2.

Claims 1-3, 7-17, 25-42, and 44-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 86-93 of copending Application No. 11/237,063 in view of Sandborn et al. (US 5,846,983) and Patel et al. (European Journal of Gastroenterology & Hepatology, 1995, 7:1037-1041, citation of record) and Yacyshyn et al. (Alimentary Pharmacology & Therapeutics, 2002, 16:1761-1770, citation of record).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the reference claims comprise almost identical, significantly overlapping method steps. Although the reference claims do not recite "pouchitis" treatment methods claimed in the instant case, the rectal delivery of ISIS 2302 into a cell in gastrointestinal track claimed in the copending application would necessarily result in the treatment effect for pouchitis, because the specification of 11/237,063 teaches that the method step can be used to treat IBD (see paragraph 0010), and because it was known in the art that pouchitis is included in IBD (see Sandborn et al.), and because ICAM-1 targeted by ISIS 2302 was known to be overexpressed in pouchitis patients as taught by Patel et al. In addition, arriving at the claimed doses, dosing schedules that result in durable remissions would have been obvious in view of the teachings of Yacyshyn et al. Hence, the scope of the instant claims and that of the reference claims overlap with each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 7-17, 25-42, and 44-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 54 and 59-63

of copending Application No. 11/720,745. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the reference claims comprise almost identical, significantly overlapping method steps, with a similar therapeutic result. Although the reference claims recite that the methods are for ameliorating "at least one indication of ulcerative colitis" and do not recite "pouchitis" claimed in the instant case, the clinical symptoms recited in lines 4-6 of claim 54 overlap with those recited in claim 1 of the instant application. Furthermore, the specification of 11/720,745 teaches that pouchitis can be treated with the same compound, ISIS 2302. See pages 7 and 10. In addition, the specification of 11/720,745 teaches that "ISIS 2302 enema" of 240 mg results in durable remissions for IBD patients. See pages 17-20. Since both the instant claims and the reference claims comprise similar method steps with a resultant effect of treating one of the similar clinical symptoms in a subject, the two sets of claims overlap in scope with each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's remarks pertaining to 11/720,745 filed on September 24, 2010 have been fully considered but they are not persuasive. Since there are no rebuttal arguments, nor is there a signed terminal disclaimer filed concurrently with the remarks, this rejection is hereby reiterated.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, 7am-3:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Heather Calamita (AU1637, Acting SPE) can be reached on 571-272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Primary Examiner
Art Unit 1635

/Dana Shin/
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